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Minnesota Board of Pharmacy

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Disciplinary Actions

The Minnesota Board of Pharmacy has concluded the following disciplinary actions during the months of September, October, and November 2003.

Pharmacists

Schroeder, Clifford E., License No. 113941-7. Licensee admitted diverting controlled substance drugs from his employer for personal use without having a valid prescription for the drugs. Licensee underwent chemical dependency treatment, enrolled in the State of Minnesota's Health Professionals Services Program, and voluntarily refrained from practicing pharmacy for six months. Licensee was placed on probation by the Board with certain conditions.

Technicians

Fleegel, Marissa A., Registration No. 705852-1. Registrant surrendered her registration as a pharmacy technician in response to allegations of controlled substance diversion.

Friedrichs, Andrew W., Registration No. 707690-1. Registrant surrendered his registration as a pharmacy technician in response to allegations of diversion of controlled substances.

Simcic, Susan L., Registration No. 707326-3. Registrant surrendered her registration as a pharmacy technician in response to allegations of diversion of controlled substances.

Renewal Reminders – Technicians

January 1, 2004, was the deadline for renewing registrations for pharmacy technicians. Any technicians who did not renew their registration by January 1 now face payment of a late fee when their registration is renewed, and are not allowed to practice as a technician without a valid technician registration.

The pharmacist-in-charge responsible for each Minnesota pharmacy is encouraged to make sure that all of the pharmacy technicians employed in his or her pharmacy have a current technician registration posted.

Pharmacists

Pharmacist license renewals were recently mailed out. Any pharmacist that did not receive a license renewal should contact the Board of Pharmacy immediately to verify the correct mailing address. Pharmacist renewals are requested to be returned by February 1, 2004. Pharmacist license renewals expire on March 1 of each year and a late fee attaches to any renewal received after March 1. As is the case with pharmacy technicians, pharmacists are not allowed to practice after March 1 without a valid license renewal.

DEA Number Confusion

Board of Pharmacy surveyors report that there still appears to be some confusion on the part of pharmacists regarding the use of a hospital Drug Enforcement Administration (DEA) number by an individual practitioner.

DEA rules in 21 CFR 1301.22 read as follows: "(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;
(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;
(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;
(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;
(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12);
(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner."

Pharmacists who receive a prescription with a practitioner's DEA number issued under the guidelines of this section may contact the hospital to verify the authenticity of the prescriber.

New Regulation Speeds Access to Generic Drugs

On August 18, 2003, Food and Drug Administration (FDA) implemented a final rule that speeds the approval of generic drugs. The final rule will limit the number of automatic 30-month stays that may delay generic drug availability. Now, a maximum of one 30-month stay will be permitted for each generic application.

The final rule clarifies the types of drug patents that can be submitted for listing in the FDA's "Orange Book" and prevents innovator drug companies from submitting certain new patent claims that are unlikely to represent substantial new innovation in order to extend their marketing protection. FDA will only allow submission of patents that claim the drug substance (active ingredient); the drug product (formulation and composition); and the method of use (injectable, tablet, etc).

The FDA is working with Congress on generic approval issues during the process of completing discussions on a Medicare drug benefit. Enactment of such a benefit may affect the implementation of some provisions for the 30-month stay included in the Final Rule, but FDA will work with Congress so product developers are not subject to multiple "regimes" of regulation of generic drug competition when the bills are passed.

Proposed Rule to Allow Electronic Orders for Controlled Substances

On June 27, 2003, the United States Drug Enforcement Administration (DEA) published a proposed rule that would allow for the electronic transmission and maintenance of orders for controlled substances as an alternative to the use of DEA Form 222 for DEA registrants who manufacture, distribute, or purchase controlled substances. With this rule, DEA hopes to establish an electronic framework for controlled substance distribution in accordance with the Government Paperwork Elimination Act of 1998 and the Electronic Signatures in Global and National Commerce Act of 2000 (E-Sign). The framework incorporates Public Key Infrastructure/digital signature technology intended to ensure the electronic system provides for message/record integrity, authentication, and nonrepudiation.

Rx Pattern Analysis Tracking Robberies and Other Losses Initiative

The National Community Pharmacists Association (NCPA), National Association of Drug Diversion Investigators (NADDI), and the Pharmaceutical Security Institute are launching an information clearinghouse for data related to pharmacy burglaries and thefts involving the loss of controlled substances. Pattern Analysis Tracking Robberies and Other Losses, or RxPATROL™ is an initiative conceived, designed, developed, and funded by Purdue Pharma, LP. The program will be able to collect, collate, analyze, and disseminate pharmacy theft information to appropriate law enforcement agencies for further action.

An RxPATROL Theft Report Form has been developed to aid non-law enforcement personnel in completing the theft report accurately and concisely. Loss Prevention personnel and independent pharmacy owners and managers will be able to access the Theft Report from the NADDI home page (www.naddi.org) as well through a link to the NCPA Web site (www.ncpanet.org). Another available service will be a timely incident analysis that will reveal trends that could potentially threaten pharmacists and pharmacy personnel. RxPATROL will provide this to NADDI, advising law enforcement and pharmacy personnel of emerging criminal trends.

NABP Wants Your Input for Testing Programs

Interested in examination item writing? If you are a pharmacy practitioner, educator, or regulator, NABP is seeking your expertise as an item writer for the North American Pharmacist Licensure Examination™, Multistate Pharmacy Jurisprudence Examination®, Foreign Pharmacy Graduate Equivalency Examination®, and the Disease State Management examinations. Those interested should send or fax a letter of interest and a current resume or curriculum vitae to NABP's Executive Director/Secretary, Carmen A. Catizone, at 700 Busse Highway, Park Ridge, IL 60068; fax 847/698-0124.

If chosen, you will receive training materials detailing the skills necessary for your designated examination, and may be asked to attend a weekend workshop at NABP Headquarters or an area hotel with applicable expenses paid by NABP. Periodically, item writers will receive requests to develop new test items that will be considered for inclusion in NABP's assessment programs.

If you are a state board of pharmacy member or staff member, you are particularly encouraged to take part in this item-writing process. Questions about item writing should be directed to Mr Catizone and/or the competency assessment director at NABP headquarters.

NABP Announces New FPGEE Administration Date, Successful June Examination

NABP is pleased to announce that December 6, 2003, will be the next administration date of the paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination locations will be released at a later date.

As with the June 2003 FPGEE administration, qualified candidates will receive registration information via United States mail. Materials were mailed to qualified candidates on July 25, 2003.

In addition, the Saturday, June 21, 2003 FPGEE administration was a success as approximately 2,040 candidates sat for the examination. NABP restarted the FPGEE on this day, offering it in four US locations: Dallas, TX; New York, NY; Northlake (Chicago area), IL; and Oakland, CA, after a security breach in October 2002 prompted a halt to the examination.

"NABP is proud to have been able to quickly isolate the compromise, secure the examination, and have a new examination

ready for administration in 2003," says Donna S. Wall, NABP president. "This involved the time and dedication of many people including volunteer item writers and NABP staff. With their efforts, NABP was able to create a new examination and process 3,000 applications in only seven months."

All FPGEE candidates who qualified to sit for the examination were sent registration forms in February 2003. Candidates were able to choose from the four US locations in order of preference. Reservations were made on a first-come, first-served basis and candidates were mailed admission tickets. Security features required candidates to present two forms of identification in addition to their admission ticket, which featured the candidate's photo; the checking of large items such as backpacks; and the posting of security guards.

Candidates who sat for the June 21 administration received their score results 10 weeks after the administration.

Candidates with questions may visit NABP's Web site at www.nabp.net for updated information or e-mail the Customer Service Department at custserv@nabp.net. Individuals without Internet access may contact NABP's Customer Service Department at 847/698-6227.

The Virtues of Independent Double Checks – They Really are Worth Your Time!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with US Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Has your double check system ever failed, leading to a medication error that escaped your detection and ultimately reached a patient? If you answered "yes" to this question, you're not alone. Here's one recent example.

A pharmacist correctly calculated the dose and volume of interferon for an infant, but entered 0.68 mL into the computer instead of the correct volume of 0.068 mL (a common mistake documented in the literature). A second pharmacist double-checked the calculation. He arrived at the correct volume of 0.068, but misread the computer entry of 0.68 by the first pharmacist as 0.068 due to "confirmation bias" – seeing only what one expects to see and overlooking any disconfirming evidence.

As this example shows, there's no question that double checks carried out by people fail at times. But have these failures led you to doubt the overall value of double check systems? Given how busy pharmacists and other health care professionals are, do you wonder if this error reduction strategy is even worth your time to carry out? We asked Dr Anthony Grasha, Professor of Psychology at the University of Cincinnati, to offer comment on this issue.

Research shows that people find about 95% of all mistakes when checking the work of others.[1,2] Mathematically, the benefit of double checks can be demonstrated by multiplying this 5% error rate during the checking process and the rate in which errors occur with the task itself (the checking error rate x the task error rate). For example, if a pharmacy dispensing error rate is 5% (based on research findings), and a double-check occurs before medications are dispensed, then the actual chance of a dispensing error reaching the patient is 5% of 5%, or only 0.25%. Human factors suggest that double checks are more effective if they are performed independently. For example, an error in prescription computer order entry will be detected more often if a second person independently checks the printed prescription label against the doctor's original prescription to verify what was entered into the computer. Sharing prior calculations or performing a double check *together* with the person who originally completed the task is fraught with problems. In these instances, if a mistake is present, the person checking the work is more easily drawn into the same mistake, especially if it appears to be correct at first glance (eg, numbers correct but decimal point placement wrong or correct drug but wrong concentration selected).

Dr Grasha also points out that the effectiveness of double check systems depends on training staff to carry them out properly – as an independent cognitive task, not a superficial routine task.

Incidentally, the McKesson Foundation has provided Dr Grasha with a grant to develop a set of pharmacy-related error-prevention tools. These are free of charge and available at www.pharmsafety.net. Check it out!

References: 1) Grasha AF, et. al. Delayed verification errors in community pharmacy. Tech Report Number 112101. Cognitive Systems Performance Lab. Contact: Tony.Grasha@UC.Edu. 2) Campbell GM. and Facchinetti N. Using process control charts to monitor dispensing and checking errors. *Am J Health-Syst Pharm* 2000; 55: 946-952.

NABP Centennial Celebration Approaching

The National Association of Boards of Pharmacy® (NABP®) will be celebrating its centennial at the 100th Annual Meeting and Centennial Celebration, April 24-27, 2004, at the Fairmont Hotel, in Chicago, IL. For the past 100 years, NABP has been building a regulatory foundation for patient safety, and it will continue to support boards of pharmacy and pharmacists in the years to come. Look for more information about NABP's Centennial Celebration on NABP's Web site at www.nabp.net.

Changes in Internship Reporting Forms

The Internship Advisory Committee to the Board of Pharmacy recently recommended a change in the reporting of internship hours by pharmacy students doing internships outside of the required college of pharmacy coursework.

In the past, interns were required to complete a blue colored notice of employment form within five days of beginning employment at each internship site. In addition, a white progress report affidavit was required to be filed with the Board at the conclusion of each segment of internship experience. A student who continued employment at the same pharmacy from June through June of the following year, for instance, would be required to file only one blue notice of employment form, but would be required to file a white progress report affidavit at the end of summer, another at the end of the fall semester at the college if the student worked over the Christmas break, another at the conclusion of the Christmas break, and yet another at the end of spring semester. All of that has now been changed.

A blue notice of employment form is still required to be filed at the beginning of employment, but, if the intern remains employed at the same pharmacy during an entire year, a white progress report affidavit only needs to be filed once a year on June 15. That one progress report affidavit will delineate all of the hours of internship accumulated at that pharmacy.

If an intern changes locations of his or her internship experience, however, the white progress report affidavit must be filed at the conclusion of the employment at the first pharmacy and a blue notice of employment must be filed at the beginning of employment at the new pharmacy.

Once-a-year filing of progress report affidavits should simplify the record-keeping process for both student interns and the Board office. Interns who are late in filing the progress report affidavits, however, will be penalized with a deduction of 10% of the reported hours for each month the progress report is late.

Internship experiences that are part of the college of pharmacy curriculum (ie, required elective rotations) are reported directly to the Board by the college of pharmacy and interns are not required to file those hours on their own.

Patient Consultation

Patient consultation – it is more than affixing an auxiliary label to a vial. The Board of Pharmacy office recently received a telephone call from a patient of a local Twin Cities pharmacy. This patient had been receiving OxyContin® for severe chronic pain the past several months from this pharmacy. Recently, this patient became concerned that he was developing a tolerance and possibly dependence to the prescribed OxyContin and spoke with his physician about trying to taper his dose with a goal of possibly eliminating the OxyContin completely.

His physician then told the patient to break the tablets he had in half and take one-half of a tablet instead of the whole tablet. As you might expect, this defeated the controlled release properties of the tablet. The patient suffered an overdose of oxycodone and had to be taken to an emergency room by his family.

The patient was rightly concerned that the physician was not aware of the potentially fatal consequence of breaking OxyContin tablets. The patient was also angry that his pharmacy had repeatedly dispensed OxyContin tablets to him without ever explaining this hazard to him. He stated that the pharmacy had affixed an auxiliary label stating that the tablets should be taken whole and not crushed or broken, but no one had explained to him the possible consequences of not following this advice. Only when the patient checked Food and Drug Administration's (FDA) Web site, after the above episode, did he discover the boxed warning required by FDA in the approved labeling for this product:

OxyContin (oxycodone hydrochloride controlled-release) tablets are to be swallowed whole and are not to be broken, chewed, or crushed. Taking broken, chewed, or crushed OxyContin tablets leads to a rapid release and absorption of a potentially fatal dose of oxycodone.

Patients have the right to expect more from a pharmacy than consultation by auxiliary label.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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